

PATENT

Appl. No. 10/693,112  
Amdt. dated July 20, 2004  
Reply to Office Action of April 21, 2004

REMARKS/ARGUMENTS

In this Amendment, claim 14 is amended, and no claims are canceled so that claims 1-2, 4-7, 9-18, 20, and 22 are pending and subject to examination.

At page 2 of the Office Action, the Examiner objects to the drawings, the first paragraph of the specification, and claim 14. In response, the drawings, the first paragraph of the specification, and claim 14 have been changed. Withdraw of the objections is requested.

Obviousness rejections

At page 3 of the Office Action, claims 1, 2, 4-7, and 9-11 are rejected as obvious over Yu (U.S. Patent No. 5,774,943) and Sheridan (U.S. Patent No. 3,508,554).

This rejection is traversed. Yu discloses an endotracheal tube with colored rings on an outer surface (c. 5, l. 5-22). Sheridan discloses an endotracheal tube with a frosted surface.

Applicants submit that Yu and Sheridan would not have been combined absent improper hindsight. However, assuming, *arguendo*, that obviousness had been established, Applicants are providing evidence of unexpected results, which is believed to be sufficient to overcome any allegation of obviousness. In particular, Applicants are submitting herewith, a Declaration Pursuant to 37 C.F.R. § 1.132 by Dr. Michael P. Sherman, one of the inventors in the present application, to provide evidence of unexpected results. In *In re Rouffett*, 47 USPQ2d 1453 1457 (Fed. Cir. 1998), the Court of Appeals for the Federal Circuit stated that such evidence can be used to overcome a *prima facie* case of obviousness.

To reject claims in an application under section 103, an examiner must show an un rebutted *prima facie* case of obviousness. See *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). In the absence of a proper *prima facie* case of obviousness, an applicant who complies with the other statutory requirements is entitled to a patent. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of nonobviousness...

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The secondary considerations are also essential components of the obviousness determination....This objective evidence of nonobviousness includes ....unexpected results created by the claimed invention, unexpected properties of the claimed invention,...and skepticism of skilled artisans before the invention....The Board must consider all of the applicant's evidence....The court reviews factual conclusions drawn from this evidence for clear error. Whether the evidence presented suffices to rebut the *prima facie* case is part of the ultimate conclusion of obviousness and is therefore a question of law.

Even assuming, *arguendo*, that the Examiner has established *prima facie* obviousness with respect to the pending claims, the evidence in the Declaration is sufficient to overcome any allegation of obviousness. The Declaration establishes that embodiments of the invention produce unexpectedly good results. For example, the Declaration states on page 2:

As noted at page 15, lines 2-6 of the specification, a prospective study was conducted over about a 17-month period. The prospective study randomly assigned infants to one of two groups based on the type of endotracheal tube used and the procedure utilized to ascertain the depth of insertion during oro-tracheal intubation. Group 1 used neonatal endotracheal tubes with single-colored (black) centimeter marks and vocal cord localizer lines (also black). Subjects in Group 1 were enrolled during the odd numbered months of the study. Group 2 had brightly colored lines placed circumferentially at 6.5, 7.5, 8.5 and 9.5 cm from the tip of the endotracheal tube. These subjects were enrolled during the even numbered months of the study. The lines on the endotracheal tube consisted of non-toxic and tightly adherent tape that was 0.25 centimeters wide. Tubes with the adherent colored tape were prepared and gas sterilized before use. ....

I believe that the prospective study shows that embodiments of the invention produce unexpected results and solve the problem of RMSBI. For example, as explained at the carryover paragraph on pages 20-21 of the specification, none of the thirty one patients using an endotracheal tube with colored lines had RMSBI, while eight of thirty-one patients using endotracheal tubes using solid black lines had RMSBI. See also, FIG. 5 in the present application. As shown by the data provided in the specification and at FIG. 5 of the present application, embodiments of the

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invention are clearly advantageous over conventional  
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Put another way, 25% (i.e., 8 out of 31) of patients using an endotracheal tube exhibited RMSBI using an endotracheal tube with only black marks (similar to Sheridan's markings), while 0% of patients exhibited RMSBI when using embodiments of the invention. Clearly, these results are both advantageous and unexpected, and they are therefore sufficient to rebut any allegation of obviousness.

Double patenting rejections

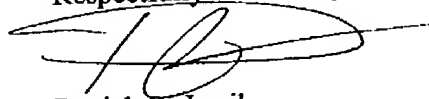
At pages 7 and 9 of the Office Action, claims 12-20, and 22 are rejected under the doctrine of obviousness double patenting in view of claims in U.S. Patent No. 6,668,832.

Although Applicants do not agree with the double patenting rejections, Applicants are obtaining and will file a Terminal Disclaimer with respect to U.S. Patent No. 6,668,832. Accordingly, withdrawal of the obviousness double patenting rejections is requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned.

Respectfully submitted,



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